

Baswell et al., namely to provide an implant with improved rate of bone tissue attachment (see page 2, lines 7-9 of this application) and now also inserted in claim 1) by chemical effect and not a morphological effect.

The minimized tissue fixation according to Baswell et al. is obtained by a method for chemically polishing medical implants made of titanium or an alloy of titanium. This chemical polishing is obtained through the use of a polishing solution comprising at least three different acids: lactic acid, hydrofluoric acid and nitric acid. The major ingredient of this polishing solution is lactic acid (about 60-79% by weight). Hydrofluoric acid is thus used in combination with other acids, which are all necessary for the invention described by Baswell et al. The method according to the invention provides implants with a smooth, matte surface, and the teaching of three acids in Baswell et al. is excluded by the "consisting essentially of" claim language used herein.

Having the teachings of Baswell et al, in mind, the teachings of the presently claimed inventions are very surprising since the effect of the method according to the inventions is completely opposite to what might be expected after the study of Baswell et al (increased bone tissue attachment compared to minimized tissue fixation).

Furthermore, according to Baswell et al, the acids are used in high concentrations resulting in very low pH values. For example, a solution of nitric acid only in a concentration of 10.5% by weight (i.e. the lowest concentration value for nitric acid given by Baswell et al.) has a pH of -0.22, which is considerably lower than the pH of solutions used according to the present invention. The solution used according to Baswell et al, comprising two more acids, thus has a much lower pH than the solution used according to the present invention.

The concentration of hydrofluoric acid in the solutions used according to the invention is much lower than the concentrations given by Baswell et al. This is necessary in order to avoid etching, which is undesirable according to the invention (see e.g. page 5, lines 10-11).

Considering the above, the teachings of Baswell et al. should not be of any particular relevance to the patentability of the invention.

Haruyaki (JP 3146679)

Similar to Baswell et al., Haruyuki bases his effects on a morphological treatment. Haruyuki thus sets out to provide irregular fine depressions in the surface of at least the embedded part of a living body-restoring member made of titanium or a titanium alloy and to enhance the adhesive strength of the member to tissue. A two-step treatment involving immersion in a hydrofluoric acid solution followed by immersion in a mixed solution of hydrofluoric acid and hydrogen peroxide is said to provide the irregular fine depressions and provide a certain anchoring effect.

The use of hydrofluoric acid alone is not contemplated by Haruyuki. Since Haruyuki stresses the combination with hydrogen peroxide, there is no reason to believe that a treatment with hydrofluoric acid alone would lead to desired results. The teaching of the two-step process in Haruyuki is excluded by the "consisting essentially of" claim language used herein.

Considering the teachings of Haruyuki, it must therefore be surprising that the treatment of a metallic implant according to the invention with a solution of only hydrofluoric acid provides an implant with an improved rate of bone tissue attachment.

Furthermore, the teachings of Haruyuki are based on a morphological effect, whereas the improved properties according to the invention are thought to be based on a chemical effect associated with fluorine retained on the surface of the implants, and no morphological effect is sought. On the contrary, as stated above, morphological effects in the form of etching is highly undesirable according to the present invention. Haruyuki gives no guidance regarding any chemical alteration of the surface of an implant.

Considering the above, the teachings of Haruyuki should not be of any particular relevance to the patentability of the present invention.

Chung U.S. Patent No. 5,039,546

Chung et al. describe a method for improving the stability of the coating strength and decreasing the biodegradation rate of a calcium phosphate based material coating formed on a metal surface. The method according to Chung et al. is thus intended for a purpose completely different from the purpose according to the present invention. The main object of the method according to Chung et al. seems to be the conversion of hydroxyapatite into fluorapatite, which is more stable in body tissues than hydroxyapatite, as it is well known to one skilled in the art.

Nothing in this document gives any indication that the method would lead to an implant with an improved rate of bone tissue attachment.

Furthermore, according to Chung et al. the fluoride ion containing solution should have a pH value greater than 3 (see column 2, lines 41-42, and claim 3) and preferably 5 or higher (see column 2, line 42, and claim 4). This differs from the teachings of the present invention, according to which the pH of the hydrofluoric acid solution (when such a solution is used) should be in the range of 1.6 to 3.0.

Considering the above, the teachings of Chung et al. should not be of any particular relevance to the patentability of the present invention.

Applicant submits that all of the claims are in condition for allowance, which action is requested. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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